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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,048	08/23/2001	C. Frank Bennett	ISPH-0567	1653

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EXAMINER	
MCGARRY, SEAN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 09/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/938,048	BENNETT ET AL.	
	Examiner	Art Unit	
	Sean R McGarry	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-8,10 and 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-8, 10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/01/04 has been entered.

Claims 1, 2, 4-6,10, and 11 remain is rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al [US 6,080,580].

The instantly claimed invention is drawn to a method for (1) identifying a gene involved in a response to a stimulus where the method comprises contacting cells with antisense from a library prior to the application of a stimulus, (2) where the response can be secretion of a compound (3) where the compound is a cytokine (4) the response is modulation of inflammation and where the response is inhibited. The method steps include: a) contacting cells capable of an inflammatory response with an antisense [library] complementary to a cytokine or growth factor before that application of an inflammation stimulus, b) determining which antisense modulates the inflammatory response, c)identifying the antisense oligonucleotide, and d) identifying one or more genes involved in an inflamatoty response wherin the genes are identified through the identity of the antisense oligonucleotide which hybridize to the one or more genes.

It is noted that the step d) appears to indicate that the step c) identification of the antisense oligonucleotides itself identifies the gene involved in the inflammatory response

Baker et al have disclosed the use of antisense from a library of antisense (see Table 1, Table 2 and Table 3, for example) targeted to TNF-α (a cytokine) which is involved in inflammation response (an inhibition of TNF-α correlates to an inhibition of a cellular inflammatory response (see column 1, for example)). It has been disclosed in columns 19-20 a method wherein various antisense oligonucleotides (from a library) were added to different subpopulations of NeoHK cells (see also Table 3, for example). The cells were then treated with growth factors. After treatment the expression of TNF-α and the secretion of THF-α was measured. It is clear from Tables 2, 3, 5, 7 and 8 that the response to the stimulus expression of TNF-α mRNA and secretion of TNF-α secretion were variably stimulated and inhibited based on the conditions used and the particular antisense used, for example. The above-mentioned tables provide identification of antisense oligonucleotides and the extent to which they inhibit, via hybridization to their target molecule, the target molecule. The prior art therefore discloses each and every step of the claimed invention.

Claims 1, 2, 7, 8, 10, and11 remain rejected under 35 U.S.C. 102(b) as being anticipated by Bennett et al [US 5,514,788].

Bennett et al have disclosed the use of antisense targeted to various cell adhesion molecules, which are involved in inflammation. Inhibition of cell adhesion

molecules inhibits inflammatory response of cells, for example (see columns 1-2, for example) Bennett et al have disclosed the inhibition of adhesion proteins such as ICAM VCAM and ELAM with antisense oligonucleotides from antisense libraries defined in Tables 1, 2, 3, and 4, for example. It has been disclosed in Example 1 VCAM, ICAM, and ELAM expression is measured after cells (subpopulations) were treated with antisense to various cell adhesion molecules prior to challenge of the cells to various cytokines. It can be seen in tables 3, 5, 4 and Example 6 the stimulation and inhibition of cell adhesion molecule expression in response to the application of various cytokines under various conditions, for example. The above tables identify antisense oligonucleotides that hybridize to and inhibit their target molecules. All the methods steps have therefor been disclosed by the prior art.

In response to applicant's arguments, filed 6/01/04, the recitation "a method for identifying one or more genes involved in an inflammatory response by a cell" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

It is noted that the prior art discloses each and every step recited in the instant claims. Applicant argues that the additional step [c]. It appears that it is quite reasonable for the step. The rejections above show that the prior art does indeed identify antisense oligonucleotides that hybridize and modulate expression of their targets. And, as per the instant claims, the identification of the antisense oligonucleotide identifies the gene as an inflammatory gene. Regardless of whether the gene was known to be involved in inflammation or not, the steps of the instant invention have been disclosed in the prior art. Since each and every limitation has been disclosed the invention does not differ from the prior art. Whether the gene was know or not known to be involved in inflammation, the gene has clearly been identified as being involved in an inflammatory response since all of the claimed method steps have been disclosed. It is unclear how the prior art differs from the claimed invention based on applicants assertion that the intention of the claimed invention is different than the prior art. The prior art clearly discloses the methods steps recited in the instant claims. The instant claims fail to provide any steps that would define over the disclosure of the prior art. Applicant has not shown that the method steps instantly recited define over the teachings of the prior art.

All claims are drawn to the same invention claimed earlier in the application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered earlier in the application. Accordingly, **THIS ACTION IS**

MADE FINAL even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (571) 272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sean R McGarry
Primary Examiner
Art Unit 1635

SRM